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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,130	01/16/2007	Akihiro Takemiya	295010US0PCT	5706
22850 7590 06/17/2010 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER CHANG, CELIA C				
ART UNIT		PAPER NUMBER		
1625				
NOTIFICATION DATE		DELIVERY MODE		
06/17/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/589,130

Applicant(s)

TAKEMIYA ET AL.

Examiner

Celia Chang

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1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 19 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/22)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

1. Applicant's election with traverse of group I species of example 130 in the reply filed on Mar 19, 2010 is acknowledged. The traversal is on the ground that no adequate reasons and/or examples have been provided to support a conclusion of patentable distinctiveness among the identified groups. This is not found persuasive because as it was delineated in the restriction requirement, the groups being identified belong to different core structure which belong to separate classes and subclasses for which without a species election cannot be ascertained. The searches for such enormous class and subclass without restriction is not co-extensive and extremely burdensome. In addition, the different core structure has been recognized in the chemical art to belong to distinctive *class* of compounds which have different utility. See CA 140:5044, at least the core structure wherein R2 is piperazine (group III) is evidenced to be kinase inhibitors i.e. a utility different from the instant application being MMP-9 inhibitors.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5, 7-9 and claims 1-4, 6 and 12 reading on the scope of claim 5 will be prosecuted. Claims 10-11 and the remaining subject matter of claims 1-4, 6 and 12 are withdrawn from consideration per 37 CFR 1.142(b).

2. Claims 1-9 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims encompassed the scope of "hydrates, water adduct or solvates" of compounds of formula I for which no description or enabling support can be found in the specification.

A survey of the specification indicated that there are no definition as to what is "Hydrates, water adduct or solvates thereof" mean. Please note that each hydrates or solvate is a different "chemical identity" and there should never be any doubt in this century as to the chemical identity of a material (see Suddon). Unlike formation of salts between a pharmaceutically acceptable acid and an organic base compound of the claims, the formation of "hydrates, water adducts or solvates" must find descriptive and enabling support for such

claimed scope because absent of specific description, one having ordinary skill in possession of compounds would not be able to offer any predictability of which one will form what hydrates, water adduct or solvate (see Braga p.3640). Further survey of the specification indicated there is no description of which solvent can form solvate with the compounds, under what condition will such solvates be obtained, and whether the solvates will have consistent properties to be considered inclusive as being a “Markush” alternative of the compounds.

No examples, no process of making, no starting material or operability can be found for any compound encompassed by the Markush formula to have the ability in forming what hydrates (hemi-, mono- etc.) water adducts or solvates. Therefore, absent of description and enabling disclosure, the specification is insufficient in supporting the “claimed” scope of “hydrates, water adduct or solvates” of the compounds.

3. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “agent” is ambiguous and rendered the claims in hybrid format. Please note that it is unclear what is the agent for prophylaxis and/or treatment of cancer is. Is it a compound which is being used for prophylaxis and/or treatment of cancer? Or is a composition containing an effective amount for prophylaxis and/or treatment of cancer? The claim encompassed both material and process of using is ambiguous.

4. The compounds and pharmaceutically acceptable salt thereof of the compounds corresponding to claims 5, 6-9 are allowable if rewritten in independent forms free from any 112 issues.

The closest prior art is Zoller et al. US 7,528,155 wherein the difference between the prior art and the instant claims is the 4-substitution on the piperidinyl ring. The instant claims are drawn to 4-aromatic moiety substituted compounds while the prior art has an alkyl, halogen, trifluoromethyl or cyclopropylene substitution and no suggestion or motivation for modification to an aromatic moiety was found.

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5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Jun. 9, 2010

/Celia Chang/
Primary Examiner
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